

Sanitized Copy

MR# 338367

RECEIVED
OPPT CBIC

2011 SEP 22 AM 11:41

September 19, 2011



Via Federal Express

United States Environmental Protection Agency - East
Attn: TSCA Section 8(e) / Room 6428
1201 Constitution Avenue, NW
Washington, DC 20004

Subject: Notice in Accordance with Section 8(e): Results of an Acute Eye Irritation Study in Rabbits with [REDACTED]
[REDACTED] [REDACTED]

Dear Sir/Madam:

[REDACTED] is submitting results of an Acute Eye Irritation Study in Rabbits with [REDACTED]
[REDACTED], conducted by [REDACTED]. The test substance is a formulation of a pesticide.

The potential of the substance to cause damage to the conjunctiva, iris or cornea was assessed by a single ocular application of 0.1 mL of the test item to one eye of one White New Zealand rabbit. About 24 hours after application the eye was rinsed with tap water.

The ocular reactions were assessed approximately 1, 24, 48 and 72 hours after application and in weekly intervals until study day 21.

The following test item-related clinical observations were recorded:

- Slight to marked corneal opacity (grade 1 to 3) with an area involved up to $> \frac{3}{4}$
- Moderate iritis (grade 1)
- Slight to severe conjunctival redness (grade 1 to 3)
- Slight to marked conjunctival chemosis (grade 1 to 3)
- Slight to severe discharge (grade 1 to 3)



Company Sanitized

Sanitized Copy

United States Environmental Protection Agency – East
September 19, 2011
Page 2

- Additional findings like small retraction in the eyelid, contracted pupil, desquamation of corneal epithelium, fluorescence positive reaction at the cornea, marginal vascularization of the cornea in a circumscribed area as well as vascularization into the central part of the cornea in a circumscribed area and injected scleral vessels in a circumscribed or circular area were noted in the animal during the observation period.

The ocular reactions were not reversible in the animal within 21 days after application. Moderate corneal opacity, grade 2 (area involved $> 0 < \frac{1}{4}$), slight conjunctival redness (grade 1), slight conjunctival Chemosis (grade 1), small retraction in the eyelid and vascularization into the central part of the cornea in a circumscribed area were still observed in this animal at study termination on day 21.

Mean scores calculated for the animal over 24, 48 and 72 hours were 1.7 for corneal opacity, 1.0 for iris lesions, 2.0 for redness of the conjunctiva and 2.0 for chemosis.

Considering the described ocular reactions as well as the average score for irritation, the test substance causes serious eye damage under the test conditions chosen.

[REDACTED] understands that reporting of results from this study under TSCA 8(e) is in accordance with EPA's policy.

Please note that a confidential version of this letter is enclosed, treating the chemical identity and company identity as Confidential Business Information.

A Confidentiality Substantiation Questionnaire is being submitted.

Sincerely,

Enclosures